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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,481

07/11/2003

Tony Hollingsworth

0685-P04356US0

8213

110 7590 04/07/2009
DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

04/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,481	Applicant(s) HOLLINGSWORTH ET AL.	
	Examiner MISOOK YU	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 8 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/22/2009 has been entered.

This Office action contains new grounds of rejection.

Election/Restrictions

Claims 1, 2, and 4-12 are pending and claims 2 and 9-12 remain withdrawn for reason of record. Claims 1, 2, and 4-8 are under consideration.

Claim Rejections - 35 USC 102, Withdrawn

The rejection of claims 1 and 4-6 under 35 USC 102(b) as being anticipated by WO 02/058450 is withdrawn because MUC1/CD (WT) of the prior art has one less amino acid at its C-terminal end (i.e. Tyr) as applicants pointed out in the response filed on 01/22/2009.

The rejection of claims under 35 USC 102(b) as being anticipated by the '643 patent is moot since the rejected SEQ ID NO: 34 has been deleted.

Double Patenting, Withdrawn

The objection of claim 6 under 37 CFR 1.75 as being a substantial duplicate of claim 5 is withdrawn because this objection of made in error. The scope of claim 6 is limited to SEQ ID NO: 47.

Claim 7 is not objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5 because the scope of claim 7 is that the claimed composition requires all three peptides.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/25827 (11-MAY-2000).

The following is alignment of the SEQ ID NO: 48 (32 amino acids) with the sequence taught by WO200025827-A2.

RESULT 10
AAY71023
ID AAY71023 standard; protein; 93 AA.
XX
AC AAY71023;
XX
DT 29-AUG-2000 (first entry)
XX
DE Human Mucin 1 (MUC-1) protein fragment #4.

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XX
 KW Human; Mucin 1; MUC-1; tumour; pMRS30 expression vector; anti-tumour;
 KW therapy; immune response; cytostatic; vaccine.
 XX
 OS Homo sapiens.
 XX
 PN WO200025827-A2.
 XX
 PD 11-MAY-2000.
 XX
 PF 18-OCT-1999; 99WO-EP007874.
 XX
 PR 30-OCT-1998; 98IT-MI002330.
 XX
 PA (MENA) MENARINI RICERCHE SPA.
 XX
 PI Parente D, Di Massimo AM, De Santis R;
 XX
 DR WPI; 2000-365410/31.
 DR N-PSDB; AAD00387.
 XX
 PT Composition containing one or more DNA molecules encoding fragments of a
 PT Mucin 1 (MUC-1) protein overexpressed in tumor cells, useful in anti-
 PT tumor therapy.
 XX
 PS Claim 16; Fig 4; 56pp; English.
 XX
 CC The present sequence is a fragment of human Mucin 1 (MUC-1), an
 antigenic
 CC protein overexpressed in tumour cells. The sequence was obtained from
 CC BT20 tumour cells. The corresponding DNA sequence is cloned into a
 pMRS30
 CC expression vector and used in pharmaceutical composition e.g. vaccine
 for
 CC inducing an antigen-specific anti-tumour immune response. Composition
 CC containing this DNA molecule is useful in anti-tumour therapy of
 patients
 CC affected with tumours characterised by high MUC-1 expression
 XX
 SQ Sequence 93 AA;

Query Match 100.0%; Score 182; DB 3; Length 93;
 Best Local Similarity 100.0%; Pred. No. 4.1e-18;
 Matches 32; Conservative 0; Mismatches 0; Indels 0; Gaps
 0;

Qy 1 HPMSEYPTYHTHGRYVPPSSTRSPYEKVSAG 32
 ||||||||||||||||||||||||||||||||
 Db 42 HPMSEYPTYHTHGRYVPPSSTRSPYEKVSAG 73

Since “the group consisting of” in claims 1 and 5, line 5 is a Markush language of alternative choice, not the transitional phrase limiting the scope of the claim to exclude

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any unrecited additional component, the amino acid sequence containing 93 amino acids taught by WO200025827-A2 anticipates the instant claims 1, 4, and 5.

Inserting “consisting of” after “an isolated MUC1 cytoplasmic tail peptide” in line 3 of claims 1 and 5, followed by deleting the coma, and “wherein” after “peptide” would obviate this rejection.

Claims 1, 4, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/57068-A1 (09-AUG-2001).

The instant SEQ ID NO: 15 is identical to the sequence taught by WO200157068-A1. Note sequence alignment below.

Title: US-10-618-481-15
Perfect score: 52
Sequence: 1 CRRKNYGQL 9

RESULT 1
AAE09535
ID AAE09535 standard; peptide; 9 AA.
XX
AC AAE09535;
XX
DT 19-NOV-2001 (first entry)
XX
DE Human mucin-1 (MUC-1) CTL epitope #1.
XX
KW Mucin-1; cytostatic; immunostimulant; cell mediated immune response;
KW carcinoma; adenocarcinoma; breast cancer; dendritic cell; vaccine;
KW gene therapy; human; MUC-1; cytotoxic T-lymphocyte; CTL epitope.
XX
OS Homo sapiens.
XX
PN WO200157068-A1.
XX
PD 09-AUG-2001.
XX
PF 01-FEB-2001; 2001WO-AU000090.
XX
PR 01-FEB-2000; 2000AU-00005369.
PR 14-JUN-2000; 2000US-00593870.

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XX
 PA (AUST-) AUSTIN RES INST.
 XX
 PI Mckenzie IFC, Pietersz GA, Apostolopoulous V;
 XX
 DR WPI; 2001-541537/60.
 XX
 PT Immunostimulant peptide, used as an anti-carcinoma vaccine, comprises a
 PT an epitope of the non-VNTR, non-leader region of a mucin.
 XX
 PS Disclosure; Page 20; 84pp; English.
 XX
 CC The patent discloses peptide or polypeptides capable of eliciting an
 CC immune response, comprising an amino acid sequence corresponding to an
 CC epitope of the non-central portion of varying numbers of an amino acid
 CC motif (VNTR), non-leader region of a mucin. The peptides of the
 CC invention, fusion proteins comprising the peptide and conjugate
 compounds
 CC with carbohydrate polymers are used to induce a cell mediated immune
 CC response against mucin in the prevention or treatment of carcinoma,
 CC preferably adenocarcinoma, most preferably breast cancer. They are also
 CC used to pulse dendritic cell for in vivo transfer and use as a vaccine.
 CC They are also used in gene therapy. The present sequence is human mucin-
 1
 CC (MUC-1) peptide which is an epitope for cytotoxic T-lymphocytes (CTL)
 XX
 SQ Sequence 9 AA;

Query Match 100.0%; Score 52; DB 4; Length 9;
 Best Local Similarity 100.0%; Pred. No. 2.9e+06;
 Matches 9; Conservative 0; Mismatches 0; Indels 0; Gaps
 0;

QY 1 CRRKNYGQL 9
 |||||
 Db 1 CRRKNYGQL 9

Allowable Subject Matter

Claims 6 and 7 are objected to as being dependent upon a rejected base claim.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
Art Unit 1642

/MISOOK YU/
Primary Examiner, Art Unit 1642